DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

60 8th Street, N.E.
Atlanta, Georgia 30309

July 2, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Larry Buckelew
President
Teleflex Surgical Group
One Weck Drive
Research Triangle Park, NC 27709

WARNING LETTER

Dear Mr. Buckelew:

An inspection of Weck Closure Systems, LLC, located in Research Triangle Park, North Carolina, was conducted between March 18 and May 21, 1997. Our investigator found that you are manufacturing and distributing a variety of hand held surgical instruments, in addition to ligation, closure, and electrosurgery products. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The investigator documented numerous significant deviations from the Good Manufacturing Practice for Medical Devices (GMPs) as set forth in Title 21 of the Code of Federal Regulations (21 CFR), Part 820. These deviations cause the devices you manufacture and distribute to be adulterated within the meaning of Section 501(h) of the Act.

You have failed to establish and implement a quality assurance program that is appropriate for the medical devices manufactured and distributed by your firm. Quality assurance procedures and controls in place failed to ensure that your products conformed with finished device specifications prior to release. Your quality assurance program failed to respond to device quality problems identified as a result of consumer complaints which were received. Your quality assurance program is responsible for identifying, recommending, and providing solutions for quality assurance problems and verifying the implementation of such solutions.

You have failed to validate the ethylene oxide (EO) sterilization process in use. You could not provide documented evidence which established a high degree of assurance that the sterilization process in use is effective and could consistently produce a product meeting its predetermined sterility specifications and quality attributes. No installation or performance qualification had

been conducted on the sterilizer. Our investigator was informed that a retrospective validation of this process was to be conducted.

Investigator Thompson reviewed the initial cycle development study data from this retrospective study. This data revealed that ECO cartridges, from Family Group 2 Master Product, were not sterile after exposure to a [redacted] minute sterilant dwell cycle. This is particularly disturbing, in light of the fact that the in-house sterilization process uses a [redacted] minute dwell. This data led to your firm's decision to stop all in-house EO sterilization. Additional testing should be performed to determine the sterility assurance level of other products from Family Group 2 which were subjected to a [redacted] minute sterilant dwell.

You have failed to establish, implement, and control manufacturing specifications and processing procedures to assure that your devices conform to their original design or any approved changes in that design. No formalized control mechanism was in place for all changes made to finished devices and their manufacturing processes. No documentation was available of any formalized review or approval of the numerous changes made to the endoscopic manual hemoclip applier. There was no documentation that any validation efforts had been made after changes in the finished device. No evaluation was made of the changes to establish that the device would continue to meet its predetermined specifications and quality attributes. There was no documentation available that these changes were provided to the new supplier of appliers. No records were available that the product from the new supplier was evaluated by Weck, as was claimed, prior to acceptance. No validation efforts have been conducted for the passivation process currently in use. This process is performed on hand held surgical instruments.

You have failed to implement appropriate procedures for finished device inspection to assure that device specifications are met prior to release for distribution. Finished device inspection of hand held surgical instruments does not routinely include dimensional inspection. No verification was available that the devices were manufactured in accordance with established specifications. No justification or rationale could be provided for a lack of such testing. A review of the device master record for the [redacted] Towel Forceps revealed two drawings for the device with different dimensions. Although some incoming dimensional inspection was reportedly done on this device, no records were available of this inspection. No documentation was available indicating which dimensions were to be measured or were considered critical by the firm.

You have failed to establish incoming inspection procedures for all devices to assure that they meet or conform to established specifications and function as designed. There were no drawings or dimensional specifications available for the Endoscopic Manual Hemoclip Appliers. The lack of an established incoming test procedure and deficient specifications were also noted for the [redacted] Septum Scissors.

Incoming inspection of hand held surgical devices failed to include any review of the metal composition certification or device history records for imported finished or semi-finished surgical instruments. No certificate of analysis for metal composition was available for these imported

devices. No heat treatment certification was available for imported finished devices. Some incoming devices were inspected and accepted even though they differed significantly from the "A" sample used for comparison purposes. The reason given for this was that they appeared to function properly.

You have failed to assure that all production and quality assurance measurement equipment is suitable for its intended purposes and capable of producing valid results. Measurement instruments utilized for incoming component testing, in process control, and finished device testing had not been calibrated in accordance with the established calibration schedule. Some calibration records indicated acceptance of calibration results when the data indicated that the device was not within established tolerances. Some records indicated that the instrument calibration was acceptable per vendor's certification. These certification reports were not always available and in one instance could not be retrieved from the vendor. Most disturbing was the observation that calibration records were not truly indicative of the work that had been performed. Records were being prepared with incorrect dates to give the appearance that instruments had been calibrated on schedule.

You have failed to maintain appropriate written records of failure investigations. Any failure of a device to meet performance specifications after it has been released for distribution must be investigated. No such failure investigations were available even though problem trends had been identified in devices. These included cracked box locks on hand held surgical instruments, activation inconsistencies on reusable shielded trocars, and scissoring or jamming of [redacted] Ligating clips. Although your firm has identified these failures and complaint trends, no failure investigation reports were available. Some complaints reviewed indicated that failure investigations were available, even though they had not been conducted.

No documentation was available to justify the labeled expiration dates on your firm's sterile products. No testing or data was available to support the labeled expiration dates for any of these products. Some limited testing was performed on the [redacted] catheter in an effort to substantiate the expiration date. There was no evidence that these tests demonstrated that the device performance was unchanged by aging and no indication that the results were acceptable.

You have failed to conduct the quality audits of your facility as required by your established procedure. No quality assurance audit schedule was prepared for 1996 or 1997. There was no documentation available of an audit of the Quality Reporting and Quality Assurance Procedures or Supplier Audit System as required by your procedures. The Quality Reporting and Quality Assurance Procedures include documentation and change control, device master record requirements, filing systems, device history records, and label controls.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. At the close of the inspection, the Inspectional Observations (FDA 483) was issued to and discussed with Frank N. Easterbrook, President, Weck Closure Systems. A copy of the FDA 483 is enclosed for your review. The specific violations noted in this letter and in the FDA 483 are symptomatic

of serious underlying problems in your firm's quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submission of devices to which the GMP deficiencies are reasonably related will be cleared until these violations have been corrected. Also, no request for Certificates For Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory actions being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Several of these observations, such as the deficient calibration records and lack of justification for expiration dates, were discussed with Weck personnel during the previous inspection in May 1996. We are cognizant of the corrective actions taken to date to include the stopping of in-house EO sterilization, temporary stoppage of production, and product recalls. Additional work and corrective action is required however, due to the serious nature of the observations encountered. Your response should be sent to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead. Please keep us apprised of the results of the additional testing being performed on Family Group 2 Product as results become available.

Sincerely yours,

Ballard H. Graham, Director
Atlanta District

Enclosure